

K031184

MAY 21 2003

**Premarket Notification  
510(k) Summary  
(As Required by 21 CFR 807.93)**

This 510(K) Summary of safety and effectiveness for the New Star Model CoolTouch<sup>®</sup> 3 Nd:YAG Surgical Laser system is submitted in accordance with the requirements of the SDMA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	New Star Lasers, Inc.
Address:	9085 Foothills Boulevard Roseville, CA 95747
Contact Person:	Donald V. Johnson
Telephone/Fax/Email:	(916) 677-1912 – Phone (916) 677-1901 – Fax <a href="mailto:djohnson@newstarlasers.com">djohnson@newstarlasers.com</a> - Email
Preparation Date:	April 14, 2003
Device Trade Name:	New Star Nd:YAG Surgical Laser Model CoolTouch <sup>®</sup> 3
Common Name:	Nd: YAG Pulsed Surgical Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX 21 CFR 878-4810
Legally Marketed Predicate Device:	New Star Lasers, Inc. Model NS-130 (CoolTouch <sup>®</sup> ) and Model CoolTouch <sup>®</sup> II Nd:YAG Laser Systems
Description of the New Star CoolTouch <sup>®</sup> Nd:YAG Laser Systems:	The New Star CoolTouch <sup>®</sup> Nd:YAG Surgical Laser Systems are ND:YAG lasers producing laser emission at 1320 nm. The lasers consists of three interconnected sections: The cabinet which houses the power supply, the cooling system, the microcontroller and the laser, the fiber optics and the handpiece.
Intended use of the New Star CoolTouch <sup>®</sup> Nd:YAG Laser Systems:	For use in dermatology for incision, excision, ablation and vaporization with hemostasis of soft tissue. For use in the treatment of fine lines and wrinkles.
Performance Data:	None
Conclusion:	The New Star CoolTouch <sup>®</sup> 3 Nd:YAG Surgical Laser System is substantially equivalent to the predicate devices, the New Star CoolTouch <sup>®</sup> and CoolTouch <sup>®</sup> II Nd:YAG laser systems.
Additional Information:	None requested at this time



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 21 2003

Mr. Donald V. Johnson  
Vice President of Operations  
New Star Lasers, Inc.  
9085 Foothills Boulevard  
Roseville, California 95747

Re: K031184

Trade/Device Name: New Star Nd:YAG Surgical Laser Model CoolTouch® 3

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general  
and plastic surgery and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: April 14, 2003

Received: April 24, 2003

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

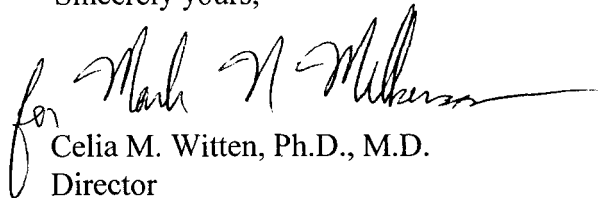
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Donald V. Johnson

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Miller", is written over the typed name of Celia M. Witten.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**510(k) Number**      Not yet assigned      K031184

**Device Name**      CoolTouch<sup>®</sup> 3

**Indications for Use**      For use in dermatology for incision, excision, ablation and vaporization with hemostasis of soft tissue. For use in the treatment of fine lines and wrinkles.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

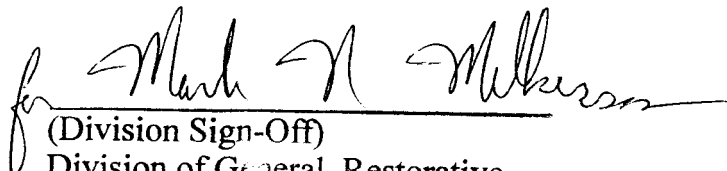
---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒   
 (Per 21 CFR 801.109)

OR

Over-the-Counter Use ☐

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number      K031184